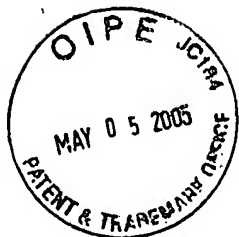


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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Group 1654

Robert P. Hammer *et al.*

Examiner Russel, Jeffrey E.

Serial No. 10/666,095

Filing Date: September 18, 2003

For: Anti-Fibril Peptides (File 0212.1 Hammer)

**RESPONSE TO ELECTION AND RESTRICTION REQUIREMENTS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

This paper is submitted in response to the April 1, 2005 action, which entered both an election of species requirement and a restriction requirement.

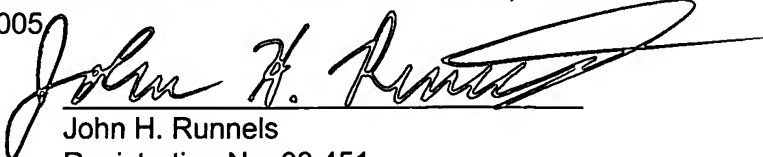
Applicants respond to below without traverse to the election of species requirement. Applicants note, however, that the non-elected species should be examined once the generic claim is found to be allowable in substance.

Applicants respectfully traverse the restriction requirement, however. It is respectfully submitted that what the April 1, 2005 action called a restriction requirement is not, in fact, a proper restriction requirement. Rather, it is actually an election of species

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**CERTIFICATE**

I hereby certify that each of the items listed above is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 2, 2005.

  
John H. Runnels  
Registration No. 33,451  
May 2, 2005

requirement as well, and it should be treated as such. Again, the non-elected species should be examined once the generic claim is found to be allowable in substance.

No amendments are presented.

For the record, Applicants do not agree that the Office's characterizations of the claimed inventions and their relationships to one another are accurate in all respects. The limitations of the respective Claims speak for themselves.

It is believed that no fee is required to submit this paper. In the event that a fee is due, please refer to the Deposit Account Authorization previously filed for this application. If any additional extension of time is required, please consider this paper a petition for the total extension of time required. See 37 C.F.R. § 1.136(a)(3).

### **Response to Election of Species Requirement**

Applicants are not traversing the election of species requirement (part 1, pp. 2-3 of the April 1, 2005 action). The absence of traversal should not be construed as agreement with particular statements made in the April 1, 2005 action concerning the election of species requirement.

Once the generic claim is found to be allowable in substance, the claims drawn to non-elected species should be rejoined and examined, regardless of whether the initial election is made with or without traversal. See M.P.E.P. §§ 809.02(c), 809.02(e), and 809.04.

### ***The Election of Species.***

In response to the election of species requirement of part 1, pp. 2-3 of the April 1, 2005 action, Applicants elect for initial examination the compound Lys-Dibg-Val-Dbzg-Phe-Dpg-(Lys)<sub>6</sub>-NH<sub>2</sub> (SEQ ID NO: 4).

Claims 1-3, 7, 8, and 19-21, and 51 read on the elected species.

Claims 22-24, 28, 29, and 40-50 read on methods for using the elected species.

### **Traversal of Restriction Requirement**

Applicants respectfully traverse the restriction requirement (part 2, pp. 3-4 of the April 1, 2005).

#### ***The Restriction Requirement Does Not Comply with M.P.E.P. § 817.***

The restriction requirement does not comply with M.P.E.P. § 817, which, among other things requires that the claims in each group be identified. The April 1, 2005 Office Action has not indicated any proposed grouping of the claims. Nor did the Office Action set forth the perceived relationship between different groups, nor did the Office Action classify the different groups, both as required by M.P.E.P. § 817.

For these reasons alone, the restriction requirement should be withdrawn.

#### ***The Restriction Requirement Does Not Comply with M.P.E.P. § 803.***

There are two separate criteria that must both be satisfied for a restriction requirement to be proper:

(1) The inventions must be independent or distinct as claimed;

and

(2) There must be a serious burden on the examiner if restriction is not required.

M.P.E.P. § 803.

The Office must establish both criteria before it may impose a proper restriction requirement. It is respectfully submitted, however, that the Office has satisfied neither of these criteria. The restriction requirement should therefore be withdrawn.

***The Office Has Not Established Distinctness of the Groups.***

The Office carries the burden of demonstrating that restriction is justified between each pair of Groups that the Office seeks to restrict from one another. The Office Action did not even clearly identify the Groups of Claims that are subject to restriction. The Action did assert that SEQ ID NOS 4, 5, 6, and 7 were distinct “because of their materially different amino acid sequences.”

With all respect, merely observing that amino acid sequences may differ is not sufficient to establish distinctness under any of the criteria of M.P.E.P. Chapter 800. It is the Office’s burden to establish that the criteria for distinctness are satisfied under M.P.E.P. Chapter 800. The Office has not satisfied this burden. Merely observing that differences exist between different subject matter is insufficient. If that were indeed the criterion, then virtually any two claims of differing scope could be restricted from one another, and few patents would ever issue containing more than a single claim.

The restriction requirement should be withdrawn for this reason alone.

***The Office Has Not Established That There Would Be a Substantial Burden if Restriction is Not Required.***

The Office also must demonstrate that there would be a substantial burden if restriction is not required. Assuming that related inventions have been shown to be distinct (which the Office has not done in this case), “the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof . . . (B) A separate status in the art when they are classifiable together . . . (C) A different field of search . . . . Where, however, the

classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.” M.P.E.P. § 808.02.

Merely observing that there are different sequences to be searched does not satisfy these criteria. There must be a completely different field of search, not just several searches to conduct within a single field.

The Office has not established that there would be a substantial burden if restriction were not required. For this reason alone, the restriction requirement should be withdrawn.

***Restriction within the members of a Markush group is not ordinarily proper, and in particular is not proper in the present application.***

M.P.E.P. § 803.02 provides in part (citations omitted):

#### **803.02 Restriction -- Markush Practice**

##### **PRACTICE RE MARKUSH-TYPE CLAIMS**

If the members of the Markush group are sufficiently few in number or are so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. . . .

[I]t is improper for the Office to refuse to examine that which the applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. . . .

A Markush-type claim can include independent and distinct inventions. . . . In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional

election will be given effect in the event that the Markush-type claims should be found not allowable. . . .

[S]hould no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. . . . The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim.

The quoted language applies precisely to the present situation, for example Claim 1 or Claim 2. Unity of invention clearly exists among the members of the Markush group of Claim 1: (1) The compounds share a common utility, namely inhibiting the toxicity of an amyloid protein or peptide; and (2) they share a substantial structural feature essential to that utility, as discussed in detail, for example, in paragraphs [0034] to [0037] of the specification.

Requiring restriction within a Markush group is ordinarily improper, although an election of species requirement might be appropriate.

### ***Summary of Traversal***

The restriction requirement should be withdrawn for any one of the following four, independent reasons: (1) The Office Action does not comply with M.P.E.P. § 817, which, among other things, requires that the claims in each group be identified. (2) The Office has not shown that the inventions are independent or distinct as claimed. (3) The Office has not shown that there would be a serious burden on the examiner if restriction were not required. (4) Restriction is ordinarily not appropriate among members of a Markush group.

### ***Provisional Election***

Applicants are uncertain how to make even a provisional election in response to the restriction requirement, because the Office has not identified how the claims are grouped for restriction purposes.

From an abundance of caution, Applicants provisionally elect that group of claims that the Office might hereafter identify as encompassing Claim 3

### **Miscellaneous**

Applicants note that Claims 1-52 are pending in this application. Through an apparent clerical error, the "Office Action Summary" (PTOL-326) accompanying the April 1, 2005 Office Action referred only to Claims "1-50."

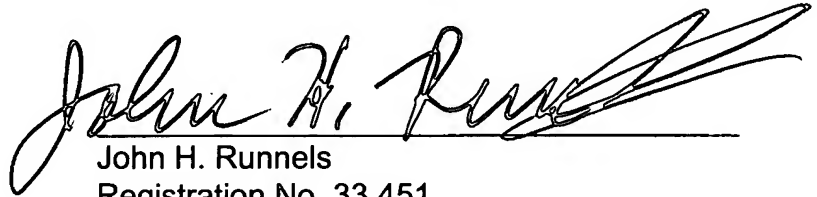
### **Conclusion**

The restriction requirement should be withdrawn, and all pending Claims should be examined on their merits.

The Examiner is respectfully advised that if the restriction requirement should be repeated, then it is the Applicants' present intention to file a formal Petition to review the propriety of the restriction requirement.

Allowance of Claims 1-52 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John H. Runnels", is written over a horizontal line.

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